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| EXAMINER | | | | |
| MERENE, JAN CHRISTOP L | | | | |
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| 3733 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/554,062

Applicant(s)

MAGERL ET AL.

Examiner

JAN CHRISTOPHER MERENE

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

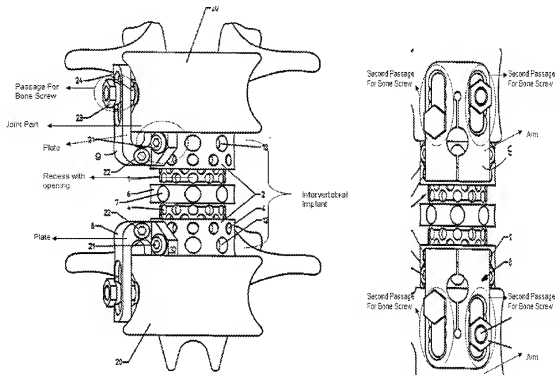
2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 6, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. **Claims 1-4, 6-8, 12** rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe 6,190,413 in view of Huebner et al US 7,090,676.

Regarding **Claim 1**, Sutcliffe discloses a device for spondylodesis and in particular for anterior intersomatic spondylodesis of the cervical spine, with at least one intervertebral implant, that functions as a pressure-absorbing spacer which stabilizes the spondylodesis and ensures that a solid osseous bridge forms between adjacent vertebral bodies and with at least one plate which is to be connected to the intervertebral implant and to an adjacent vertebra, wherein the intervertebral implant has a recess that has an opening to an outside of the implant, wherein the intervertebral

implant is connected to at least two plates, wherein the intervertebral implant extends transversely to the at least two plates which are arranged at a distance from one another, one end of each of the two plates forming a fixable joint together with the intervertebral implant (as seen in Figs below).



Sutcliffe also teaches:

in **Claim 2**, at least one of the plates has a Z-shaped, I-shaped or L-shaped configuration (as seen in Fig. 4A-B, where the plate has an L-shape);

in **Claim 3**, at least one plate, in a central area extending transversely with respect to the longitudinal axis of the spinal column, has at least one passage for a bone screw, so that this plate can be connected to a vertebra (see Figs above);

in **Claim 4**, in that said area has two passages arranged at a distance from one another and each intended for a bone screw (see Figs above);

in **Claim 6**, in that at least two plates are each connected to an intervertebral implant via a polyaxial joint (see Fig above, where when the screw is loose would provide a polyaxial joint and secured when fully fastened).

in **Claim 7**, in that at least two L-shaped plates are connected to an intervertebral implant (as seen in Fig above);

in **Claim 8**, in that the two plates each have, in an arm extending transversely with respect to the longitudinal direction of the spinal column, at least two passages which are arranged at a distance from one another and each receive a bone screw (see Fig above);

in Claim 12, that it is provided for spondylodesis of the cervical spin (see Fig above and see Col 1 lines 1-5, where the device can be used in for spondylodesis).

However, Sutcliffe does not explicitly disclose at least one plate has, at least at one end, a hemispherical joint part formed as a unit with and protruding transversely from said at least one plate, and wherein said joint part has a passage for a locking screw and engages in a hemispherical depression of an intervertebral implant to form a ball joint.

However, Huebner discloses at least one plate (#84) with a hemispherical joint part formed as a unit wherein said joint part has a passage for locking screw and engages in a hemispherical depression (#128) with a corresponding locking screw (#112) with a hemispherical underside (#126 as seen in Figs 5-6 and see Col 8 lines 40-50, where ball joints allows the plates to be pivoted).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plates of Sutcliffe to include the ball joint with the hemispherical depression with the corresponding locking screw as taught by Huebner et al (as discussed above), wherein at least two plates are each connected to an intervertebral implant via a ball joint, because a ball joint allows it allows for pivotal movements of the plate (see Col 8 lines 40-50, wherein the locking screw had a screw head #126 which is hemispherical to accommodate the depression #128).

3. **Claims 9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe 6,190,413 and Huebner et al US 7,090,676 as applied to claim 1 above, and further in view of Kirschman et al US 2005/0071006 and Lowery et al US 5,364,399.

Sutcliffe and Huebner discloses the claimed invention as stated above but does not specifically disclose that two intervertebral implants are provided which are connected to one another by a Z-shaped plate and on each of which an L-shaped or I-shaped plate is secured.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sutcliffe and Huebner to include another intervertebral implant, with corresponding L-shaped plate because it can help stabilize the spine at another location (see Col 1 lines 10-20). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a second device of Sutcliffe and Huebner, since it has been held that mere

duplication of the essential working parts of a device involves only routine skill in the art.
St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

However Kirschman discloses a similar device with at least two implants (#32) with a first and second plate (#50, #48) that are connected to each other by a plate (#32) and as seen in Fig 7,11).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sutcliffe and Huebner to include another device with another implant and plates of Sutcliffe and Huebner, as taught by Kirschman because it can help stabilize the spine in another area as well as provide for multiples areas for promoting fusion (see paragraph 51), where a plate (#32) connects the implants and facilitates in fixing a relative relation among or between spinal bones (see paragraph 9).

However, Kirschman does not specifically disclose the use of a Z-shaped plate.

It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have a Z-shaped plate, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of connecting two implants together. In re Dailey and Eilers, 149 USPQ 47 (1966).

Furthermore, Lowery et al teaches a Z-shaped plate (as seen in Fig 2).

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plate of Kirschman to be Z-shaped because it

allows for a reduced incursion into surrounding tissue (see Col 8 line11-26), where the plate would connect the two implants, where each implant has an L-shaped plate attached thereto. (With regards to "being designed as polyaxial joints," the examiner notes that the applicant has not positively recited a "polyaxial joint," only that that the connections can be designed as a polyaxial joint).

4. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe 6,190,413 and Huebner et al US 7,090,676 as applied to claim 1 above, and further in view of Lawson US 6,074,423.

Sutcliffe and Huebner discloses the claimed invention as stated above but does not appear to explicitly disclose at least one plate and/or an intervertebral implant is/are made of a material transparent to X- rays.

However, Lawson discloses an intervertebral implant that made of a material transparent to X- rays (see Col 5 lines 63-67 and Col 6 lines 1-6, where an implant is made from materials that are transparent to x-rays, such as ultrahigh molecular weight polyethylene, or other biocompatible, nonmetallic material).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Sutcliffe to include the transparent x-ray material as taught Lawson because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

5. **Claims 13-14, 16-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe 6,190,413 and Huebner et al US 7,090,676, as applied to claims 1 above, and in further view of Karpf US 5,000,166 and Lowery et al US 5,364,399.

Sutcliffe and Huebner disclosed the claimed invention as discussed above, with at least one L-shaped (as seen in Fig above), an intervertebral implant with two bores, a plurality of locking screws and bone screws (see above, where the implant and plates each have at least one joint part, where the locking screws are ball-head screws having a screw head which is substantially hemispherical on its underside (as taught by Huebner) but does not specifically disclose a kit.

However, Karpf discloses a kit with a similar device with plates and screws (as seen in Figs 1-4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to produce a kit with the plurality of elements discussed above as taught by Karpf because it applies a known technique to a known device ready for improvement to yield predictable results of providing various components to accommodate different patients (see Col 1 lines 55-64, Col 2 lines 26-30).

Furthermore, Sutcliffe and Huebner does not specifically disclose an Z-shaped plate.

However, Lowery discloses a Z-shaped plate (as seen in Fig 2).

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify at least one of the plates, in particular the back side

of the plate which attaches to the vertebra (as seen in Fig. 9) of Sutcliffe to be Z-shaped as taught by Lowery because the z-shaped profile allows for a reduced incursion into surrounding tissue (see Col 8 line11-26).

6. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe 6,190,413, Huebner et al US 7,090,676, Lowery et al US 5,364,399, and Karpf US 5,000,166, as applied to claim 13 above, in further view of Lawson US 6,074,423.

Sutcliffe, Huebner, Lowery and Karpf disclosed the claimed invention as discussed above but does not specifically disclose the implant and the plates are made out of a material transparent to x-rays.

However, Lawson teaches the use of an implant with material transparent to X-rays (see Col 5 lines 63-67 and Col 6 lines 1-6, where an implant is made from materials that are transparent to x-rays, such as ultrahigh molecular weight polyethylene, or other biocompatible, nonmetallic material).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant and plates to include the transparent x-ray material as taught Lawson because it would allow for better x-ray assessment of the bone-graft and healing of fusion following cage placement it may be advantageous to use materials with responses substantially different from bone for CAT and MRI imaging (see Col 5 lines 63-67 and Col 6 lines 1).

Response to Arguments

7. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733